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Dykema Docket No. 065379-0053

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Joerg ROSENBERG et al.)	Examiner:	Jennifer Y. CHO
Serial No.:	10/539,505)	Group Art Unit:	1621
Filed:	December 16, 2003)	Confirmation No.:	4705
For:	Formulation Comprising Fenofibric Acid,)		
	A Physiologically Acceptable Salt or)		
	Derivative Thereof)		

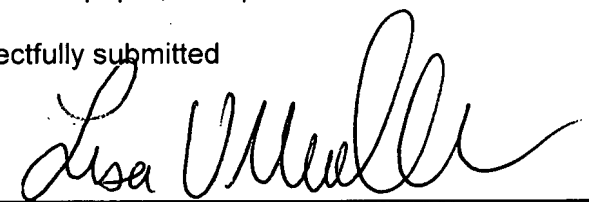
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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Attached Form PTO/SB/08A lists references which may be considered to be material to the above-identified application by the Patent Examiner. Entry into the record is respectfully requested. You are hereby authorized to charge the fee of \$180.00 and if any additional fees are incurred as a result of the filing of this paper, to deposit account number: 04-2223.

Respectfully submitted

By 
Lisa V. Mueller, Reg. No. 38,978

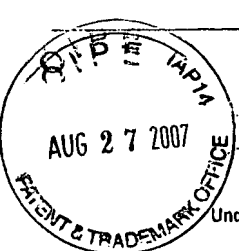
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08/28/2007 00000018 042223 10539505
01 FC:1606 180.00 DA



PTO/SB/08a (08-03)

Approved for use through 07/31/2008. OMB 0651-0031

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2003-12-16
First Named Inventor	Rosenberg, et al.
Art Unit	1621
Examiner Name	Jennifer Y. Cho
Attorney Docket Number	065379-0053

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5179097		1993-01-12	Angres, Isaac	
	2	4160020		1979-07-03	Alza Corporation	
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	6	6284803		2001-09-04	BASF Aktiengesellschaft	
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	8	4372954		1983-02-08	Moreau, Pierre et al.	

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9	4235896		1980-11-25	Orchimed S.A.	
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20	4088864		1978-05-09	Alza Corporation	
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	32	4803081		1989-02-07	Aktiebolaget Hassle	
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U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20010006662		2001-07-05	Krill, Steven et al.	
	2	20030077297	A1	2003-04-24	Chen, Feng-Jing, et al.	
	3	20050008704		2005-01-13	Ray, et al.	
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FOREIGN PATENT DOCUMENTS

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	1	474039	ES		1979-05-01			<input type="checkbox"/>
	2	2494112	FR		1982-05-21	Laruelle, Claude		<input type="checkbox"/>
	3	0173293	EP	B1	1991-10-30	Merrell Dow Pharmaceuticals Inc.		<input type="checkbox"/>
	4	01/03693	WO	A1	2001-01-18	Laboratoires Des Produits Ethiques Ethypharm		<input type="checkbox"/>
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	6	2004/054568	WO	A1	2001-07-01	Abbott GMBH & Co. Kg		<input type="checkbox"/>

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7	1416295	GB	1975-11-26	Mieville, Andre	<input type="checkbox"/>
8	1570488	GB	1980-07-02	Brisson, Henri, et al.	<input type="checkbox"/>
9	98/05331	WO	1998-02-12	Ligand Pharmaceuticals Incorporated	<input type="checkbox"/>
10	2004028506	WO	2004-04-08		<input type="checkbox"/>

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	International Conference on Harmonisation; Guideline for the Photostability Testing of New Drug substances and Products; Availability, Federal Register, Part II, Department of Health and Human Services, May 16, 1997, 27115-22, Vol. 62, No. 95	<input type="checkbox"/>
	2	Photochemical Reactions, Solid-State Chemistry of Drugs, 2nd edition, 1999, 391-416, SSCI, Inc., West Lafayette, Indiana	<input type="checkbox"/>
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6	PRICE, S.L. et al., The computational prediction of pharmaceutical crystal structures and polymorphism, Advanced Drug Delivery Reviews, 2004, 301-319, Vol. 56	<input type="checkbox"/>
7	NORD, K. et al., Photoreactivity of biologically active compounds. XII. Photostability of polymorphic modifications of chloroquine diphosphate, Drug Stability 1997, 243-248, Vol. 1, No. 4	<input type="checkbox"/>
8	MATSUDA, Y. et al., Pharmaceutical evaluation of carbamazepine modifications: comparative study for photostability of carbamazepine polymorphs by using Fourier-transformed reflection-absorption infrared spectroscopy and colorimetric measurement, J. Pharm. Pharmacol., 194, 162-167, Vol. 46	<input type="checkbox"/>
9	MATSUDA, Y. et al., Physicochemical characterization of furosemide modifications, International Journal of Pharmaceutics 1990, 11-26, Vol. 60	<input type="checkbox"/>
10	LIU, X et al., Inclusion of acitretin into cyclodextrins: phase solubility, photostability, and physicochemical characterization, Journal of Pharmaceutical Sciences, 2003, 2449-2457, Vol. 92, No. 12	<input type="checkbox"/>
11	HARRIS, K.D. et al., Probing polymorphism and reactivity in the organic solid state using ¹³ C NMR spectroscopy: studies of p-formyl-trans-cinnamic acid, Journal of Solid State Chemistry, 1991, 197-205, Vol. 93	<input type="checkbox"/>
12	EL-SHAFEI, A. et al., Semi-empirical molecular orbital methods in the design of organic colorants, AATCC Review, 2001, 23-26, Vol. 1, NO. 12	<input type="checkbox"/>
13	GREENHILL, J.V., Is the photodecomposition of drugs predictable?, Photostability of Drugs and Drug Formulations, [International Meeting on Photostability of drugs], 1st, Oslo, June 1995 (1996), Meeting Date 1995, 83-110, Publisher: Taylor & Francis, London, UK	<input type="checkbox"/>
14	COHEN, M.D. et al., IIE. Influence of crystal structure on reactivity; Structure-Sensitive reactions of organic crystals, Proc. Intern. Symp. Reactivity Solids, 4th Amsterdam, 1981, 556-562,	<input type="checkbox"/>
15	NAKANISHI F. et al., Preparation of p-phenylenediacrylic acid salts and their photoreaction in the solid state, Kenkyu Hokoku-Sen'i Kobunshi Zairyo Kenkyusho, 1982, 39-43, Vol. 133	<input type="checkbox"/>
16	ALBINI, A. et al., Photochemistry of Drugs, Handbook of Photochemistry and Photobiology, 2003, 147-193, American Scientific Publishers, Stevenson Ranch, California	<input type="checkbox"/>

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17	BOSCA, F. et al., A Laser flash photolysis study on fenofibric acid, Photochemistry and Photobiology, 1999, 853-857, Vol. 70, No. 6	<input type="checkbox"/>
If you wish to add additional non-patent literature document citation information please click the Add button		
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	8/23/2007
Name/Print	Lisa V. Mueller	Registration Number	38,978

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